



PTO/SB/08A (08-03)  
Approved for use through 07/31/2006. OMB 9551-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO			<b>Complete If Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Application Number</b>	10/567,298	
			<b>Filing Date</b>	February 6, 2006	
			<b>First Named Inventor</b>	M. Ian Phillips	
			<b>Art Unit</b>	4645 1632	
			<b>Examiner Name</b>	/Wu-Cheng Winston Shen/	
<b>Sheet</b>	1	of	5	<b>Attorney Docket Number</b>	USF-2007CXZ1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number - Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-10/567,275	02-06-2006	Phillips et al. (patent application)	All
	U	US-			
	U	US-			
	U	US-			
	U	US-			
	U	US-			
	U	US-			
	U	US-			
	U	US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
	F1	WO 2005/017165 A1	02-24-2005	Univ. of South Florida	All	
	F2	WO 2004/024867 A2	03-25-2004	Univ. of Florida	All	
	F3	WO 00/50048 A3	08-31-2000	Univ. of Pittsburgh	All	
	F					
	F					
	F					
	F					

<b>Examiner Signature</b>	/Wu-Cheng Winston Shen/	<b>Date Considered</b>	01/23/2009
---------------------------	-------------------------	------------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-785-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	10/567,298
(use as many sheets as necessary)		Filing Date	February 6, 2006
		First Named Inventor	M. Ian Phillips
		Group Art Unit	4645 1.632
		Examiner Name	/Wu-Cheng Winston Shen/
		Attorney Docket Number	USF-200TCXZ1
Sheet	2	of	5

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R1	ABRUZZESE, R. et al. "Ligand-dependent regulation of vascular endothelial growth factor and erythropoietin expression by a plasmid-based autoinducible GeneSwitch system" <i>Mol. Therapy</i> , 2000, 2:276-287.	
	R2	CHEN, H. et al. "Protection against ischemia-reperfusion injury and myocardial dysfunction by antisense-oligodeoxynucleotide by antisense-oligodeoxynucleotide directed at angiotensin-converting enzyme mRNA" <i>Gene Ther.</i> , 2001, 8:804-810.	
	R3	CHEN, H. et al. "Protection against myocardial dysfunction induced by global ischemia-reperfusion by antisense-oligodeoxynucleotides directed by $\beta_1$ -adrenoceptor mRNA" <i>J. Pharmacol. Exp. Ther.</i> , 2000, 294:722-727.	
	R4	CONGET, P.A. and MINGUELL, J.J. "Adenoviral-mediated gene transfer into ex vivo expanded human bone marrow mesenchymal progenitor cells" <i>Exp. Hematol.</i> , 2000, 28:382-390.	
	R5	DAVANI, S. et al. "Mesenchymal progenitor cells differentiate into an endothelial phenotype, enhance vascular density, and improve heart function in a rat cellular cardiomyoplasty model" <i>Circulation</i> , 2003, 108(Suppl. 1):II253-II258.	
	R6	FRANZ, W.M. et al. "Heart-specific targeting of firefly luciferase by the myosin light chain-2 promoter and developmental regulation in transgenic mice" <i>Circ. Res.</i> , 1993, 73:629-638.	
	R7	GINGER, E. et al. "Specific DNA binding of GAL4, a positive regulatory protein of yeast" <i>Cell</i> , 1985, 40:767-774.	
	R8	GU, J. et al. "Tumor-specific transgene expression from the human telomerase reverse transcriptase promoter enables targeting of the therapeutic effects of the Bax gene to cancers" <i>Cancer Res.</i> , 2000, 60:5359-5364.	
	R9	HABERMAN, R. et al. "Inducible long-term gene expression in brain with adeno-associated virus gene transfer" <i>Gene Therapy</i> , 1998, 5:1604-1611.	
	R10	HALABY, I. et al. "Glucocorticoid-regulated VEGF expression in ischemic skeletal muscle" <i>Mol. Therapy</i> , 2002, 5:300-306.	
	R11	HUANG, L.E. et al. "Regulation of hypoxia-inducible factor 1 $\alpha$ is mediated by an O <sub>2</sub> -dependent degradation domain via the ubiquitin-proteasome pathway" <i>Proc Natl Acad Sci USA</i> , 1998, 95:7987-7992.	
	R12	KAGIYAMA, T. et al. "Expression of angiotensin type 1 and 2 receptors in brain after transient middle cerebral artery occlusion in rats" <i>Regul. Pept.</i> , 2003, 110:241-247.	
	R13	KEEGAN, L. et al. "Separation of DNA binding from the transcription-activating function of a eukaryotic regulatory protein" <i>Science</i> , 1986, 231:699-704.	

Examiner Signature	/Wu-Cheng Winston Shen/	Date Considered	01/23/2009
--------------------	-------------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/567,298
Filing Date	February 6, 2006
First Named Inventor	M. Ian Phillips
Group Art Unit	<del>4045</del> 1632
Examiner Name	/Wu-Cheng Winston Shen/
Attorney Docket Number	USF-200TCXZ1

Sheet	3	of	5
-------	---	----	---

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R14	KIMURA, B. <i>et al.</i> "Attenuation of hypertension and heart hypertrophy by adeno-associated virus delivering angiotensinogen antisense" <i>Hypertension</i> , 2001, 37:376-380.	
	R15	KIRCHHEIS, R. <i>et al.</i> "Polyethylenimine/DNA complexes shielded by transferring target gene expression to tumors after systemic application" <i>Gene Ther.</i> , 2001, 8:28-40.	
	R16	KOH, G.Y. <i>et al.</i> "Targeted expression of transforming growth factor- $\beta$ 1 in intracardiac grafts promotes vascular endothelial cell DNA synthesis" <i>J. Clin. Invest.</i> , 1995, 95:114-121.	
	R17	KOLLET, O. <i>et al.</i> "HGF, SDF-1, and MMP-9 are involved in stress-induced human CD34 <sup>+</sup> stem cell recruitment to the liver" <i>J. Clin. Invest.</i> , 2003, 112:160-169.	
	R18	MANGI, A.A. <i>et al.</i> "Mesenchymal stem cells modified with Akt prevent remodeling and restore performance of infarcted hearts" <i>Nat. Med.</i> , 2003, 9:1195-1201.	
	R19	MELO, L. <i>et al.</i> "Gene therapy strategy for long-term myocardial protection using adeno-associated virus-mediated delivery of heme oxygenase gene" <i>Circulation</i> , 2002, 105:602-607.	
	R20	OGRIS, M. <i>et al.</i> "The size of DNA/transferring-PEI complexes is an important factor for gene expression in cultured cells" <i>Gene Ther.</i> , 1998, 5:1425-1433.	
	R21	PHILLIPS, M.I. "Gene therapy for hypertension: Antisense inhibition with adeno-associated viral vector delivery targeting angiotensin II type 1 receptor messenger ribonucleic acid" <i>Am. J. Cardiol.</i> , 1998, 82(10A):60S-62S.	
	R22	PHILLIPS, M.I. "Somatic gene therapy for hypertension" <i>Braz. J. Med. Biol. Res.</i> , 2000, 33:715-721.	
	R23	PHILLIPS, M.I. "Is gene therapy for hypertension possible?" <i>Hypertension</i> , 1999, 33:8-13.	
	R24	PHILLIPS, M.I. "Gene therapy for hypertension: The preclinical data" <i>Hypertension</i> , 2001, 38(3 Pt 2):543-548.	
	R25	PHILLIPS, M.I. "Gene therapy for hypertension: sense and antisense strategies" <i>Expert. Opin. Biol. Ther.</i> , 2001, 1(4):655-662, abstract.	
	R26	PHILLIPS, M.I. <i>et al.</i> "Vigilant vector: Heart-specific promoter in an adeno-associated virus vector for cardioprotection" <i>Hypertension</i> , 2002, 39(2 Pt 2):651-655.	

Examiner Signature	/Wu-Cheng Winston Shen/	Date Considered	01/23/2009
--------------------	-------------------------	-----------------	------------

\*EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/567,298
Filing Date	February 6, 2006
First Named Inventor	M. Ian Phillips
Group Art Unit	<del>4645</del> 1632
Examiner Name	/Wu-Cheng Winston Shen/
Attorney Docket Number	USF-200TCXZ1

Sheet	4	of	5
-------	---	----	---

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	R27	PHILLIPS, M.I. "Gene therapy for hypertension: The preclinical data" <i>Methods Enzymol.</i> , 2002, 346:3-13.	
	R28	PONNAZHAGAN, S. <i>et al.</i> "Adeno-associated virus type 2-mediated transduction of murine hematopoietic cells with long-term repopulating ability and sustained expression of a human globin gene in vivo" <i>J. Virology</i> , 1997, 71:3098-3104.	
	R29	QIAO, J. <i>et al.</i> "Tumor-specific transcriptional targeting of suicide gene therapy" <i>Gene Therapy</i> , 2002, 9:168-175.	
	R30	RUAN, H. <i>et al.</i> "A hypoxia-regulated adeno-associated virus vector for cancer-specific gene therapy" <i>Neoplasia</i> , 2001, 3:255-263.	
	R31	SCHMITZ, M.L. and BAEUERLE, P.A. "The p65 subunit is responsible for the strong transcription activating potential of NF- $\kappa$ B" <i>EMBO J.</i> , 1991, 10:3805-3817.	
	R32	SEMENZA, G.L. <i>et al.</i> "Hypoxia response elements in the aldolase A, enolase 1, and lactate dehydrogenase A gene promoters contain essential binding sites for hypoxia-inducible factor 1" <i>J. Biol. Chem.</i> , 1996, 271:32529-32537.	
	R33	SHAKE, J.G. <i>et al.</i> "Mesenchymal stem cell implantation in a swine myocardial infarct model: engraftment and functional effects" <i>Ann. Thorac. Surg.</i> , 2002, 73:1919-1926.	
	R34	SIRTORI, C.R. "New targets for lipid lowering and atherosclerosis prevention" <i>Pharmacol. Ther.</i> , 1995, 67:433-447.	
	R35	SMITH-ARICA, J.R. <i>et al.</i> "Switching on and off transgene expression within lactotrophic cells in the anterior pituitary gland in vivo" <i>Endocrinology</i> , 2001, 142:2521-2532.	
	R36	STRAUER, B.E. and KORNOWSKI, R. "Stem cell therapy in perspective" <i>Circulation</i> , 2003, 107:929-934.	
	R37	TANG, X. <i>et al.</i> "Intravenous angiotensinogen antisense in AAV-based vector decreases hypertension" <i>Am. J. Physiol.</i> , 1999, 277(6 Pt 2):H2392-H2399.	
	R38	TANG, Y.L. <i>et al.</i> "Paracrine action enhances the effects of autologous mesenchymal stem cell transplantation on vascular regeneration in rat model of myocardial infarction" <i>Ann Thorac. Surg.</i> , 2005, 80:229-237.	
	R39	TANG, Y.L. <i>et al.</i> "A hypoxia-inducible vigilant vector system for activating therapeutic genes in ischemia" <i>Gene Ther.</i> , 2005, 12:1163-1170.	

Examiner Signature	/Wu-Cheng Winston Shen/	Date Considered	01/23/2009
--------------------	-------------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on and amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/567,298
Filing Date	February 6, 2006
First Named Inventor	M. Ian Phillips
Group Art Unit	4646 1.632
Examiner Name	/Wu-Cheng Winston Shen/
Attorney Docket Number	USF-200TCXZ1

Sheet 5 of 5

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R40	TANG, Y. <i>et al.</i> "Hypoxia inducible double plasmid system for myocardial ischemia gene therapy" <i>Hypertension</i> , 2002, 39(2 Pt 2):695-698.	
	R41	TANG, Y.L. <i>et al.</i> "Protection from ischemic heart injury by a vigilant heme oxygenase-1 plasmid system" <i>Hypertension</i> , 2004, 43:746-751.	
	R42	TANG, Y.L. <i>et al.</i> "Improved graft mesenchymal stem cell survival in ischemic heart with a hypoxia-regulated heme oxygenase-1 vector" <i>J. Am. Coll. Cardiol.</i> , 2005, 46:1339-1350.	
	R43	TANG, Y.L. <i>et al.</i> "A vigilant, hypoxia-regulated heme oxygenase-1 gene vector in the heart limits cardiac injury after ischemia-reperfusion in vivo" <i>J. Cardiovasc. Pharmacol. Ther.</i> , 2005, 10:251-263.	
	R44	TANG, Y. <i>et al.</i> "Vigilant vectors: adeno-associated virus with a biosensor to switch on amplified therapeutic genes in specific tissues in life-threatening disease" <i>Methods</i> , 2002, 28:259-266.	
	R45	TANG, Y.L. <i>et al.</i> "Autologous mesenchymal stem cell transplantation induce VEGF and neovascularization in ischemic myocardium" <i>Regul. Pept.</i> , 2004, 117:3-10.	
	R46	TANG, Y.L. <i>et al.</i> "Mobilizing of haematopoietic stem cells to ischemic myocardium by plasmid mediated stromal-cell-derived factor-1a (SDF-1a) treatment" <i>Regul. Pept.</i> , 2005, 125:1-8.	
	R47	WOO, Y.J. <i>et al.</i> "Recombinant adenovirus-mediated cardiac gene transfer of superoxide dismutase and catalase attenuates postischemic contractile dysfunction" <i>Circulation</i> , 1998, 98:11255-11261.	
	R48	WU, P. <i>et al.</i> "Adeno-associated virus vector-mediated transgene integration into neurons and other nondividing cell targets" <i>J. Virol.</i> , 1998, 72:5919-5926.	
	R49	YAMAGUCHI, J. <i>et al.</i> "Stromal cell-derived factor-1 effects on ex vivo expanded endothelial progenitor cell recruitment for ischemic neovascularization" <i>Circulation</i> , 2003, 107:1322-1328.	
	R50	YANG, B.C. <i>et al.</i> "Critical role of AT1 receptor expression after ischemia/reperfusion in isolated rat hearts: Beneficial effect of antisense oligodeoxynucleotides directed at AT1 receptor mRNA" <i>Circ. Res.</i> , 1998, 83:552-559.	
	R51	YANG, B.C. <i>et al.</i> "Increase in angiotensin II type 1 receptor expression immediately after ischemia-reperfusion in isolated rat hearts" <i>Circulation</i> , 1997, 96:922-926.	
	R52	ZVARITCH, E. <i>et al.</i> "The transgenic expression of highly inhibitory monomeric forms of phospholamban in mouse heart impairs cardiac contractility" <i>J. Biol. Chem.</i> , 2000, 275:14985-14991.	

Examiner Signature	/Wu-Cheng Winston Shen/	Date Considered	01/23/2009
--------------------	-------------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.